

**REMARKS**

The Examiner's action dated July 11, 2003, has been received, and its contents carefully noted.

In order to advance prosecution, claims 1 and 10 have been amended to more clearly define the contribution of the invention over the prior art.

The rejection presented in section 2 of the action is traversed for the reason that the pending claims, and particularly independent claims 1 and 10, define cleaning devices that are not disclosed in or suggested by the applied reference.

The cleaning unit disclosed in the applied reference, and in particular shown in figure 1A thereof, is composed of a housing 14 that encloses a needle assembly receiving channel 24, a waste discharge channel 26 and a cross channel 30 permanently connecting channels 24 and 26 together. The needle assembly includes a needle 38 that extends through a needle channel 36. When cleaning fluid is being introduced into a header through needle 38, waste fluid can flow from the header and through needle channel 36, around needle 38.

The operation of this device is described in the following passage appearing at column 21, lines 31-47:

In operation, the precleaner header 10, 210 is preferably connected to i) a source for an incoming stream 100 by the fluid inlet connector 60, 390, ii) a waste drain for the waste stream 104 by the waste discharge connector 54, 392, and iii) a dialyzer 98 by the coupling arm 20, 220. The incoming stream 100 flows through the fluid inlet connector 60, 390, through the needle assembly 22, 222, through the needle 38, 238, out the fluid discharge perforation 28, 228, into the dialyzer header cap 12 and dialyzer header 106, cleaning the buildup 102 from the dialyzer header cap 12 and the dialyzer header 106 including the lumen openings 116 and the hollow fibers 114, forming a waste stream 104. The waste stream 104 flows from the dialyzer header 106, through the dialyzer header cap 12, into the needle assembly receiving channel 24, 224, through the waste discharge channel 26, 226, through the waste discharge outlet connector 54, 392, to a waste drain.

In the system disclosed by Arnal, clots are simultaneously loosened and removed through the "precleaner header" and through the waste discharge outlet channel. In use, it is possible for a blockage to occur in the waste discharge outlet channel (**26** or **18** or **104** of Figure 6), especially during a reverse flush step. This would cause the pressure in the header to increase as fluid and air enter the header from the fluid inlet path, so that when the fluid inlet flow is turned off this can result in waste fluid being pushed

through the needle back to the fluid inlet path **16** and **100**. If one dialyzer is removed from the system and a new dialyzer inserted, the waste fluid that entered the inlet path (**16** and **100**) will be introduced to the new dialyzer and result in a significant risk of cross contamination.

Cleaning devices according to the present invention include a flow directing element that is movable between a cleaning position and a back flush position in response to flow of fluid through a passage and the flow directing element is constructed such that when moved into the cleaning position by fluid flowing to its fluid flow inlet, fluid can flow through the passage only in one direction toward the end of the housing that is to be connected to the header. The flow directing element is also movable into the back flush position in response to flow of fluid through the passage from the header, or the flow outlet end of the flow directing element, to provide a back flush flow path only when the flow directing element is in the back flush position.

Since fluid can flow only in one direction when the flow directing has been moved by flowing fluid into the cleaning position, backward flow of waste fluid through the passage cannot occur, and thus the prior art problems described above are avoided. Flow can occur in the reverse

direction only when desired and, in particular, when the forward flow of cleaning fluid has been terminated.

In the Arnal device, in clear contrast to the present invention, waste fluid can flow through needle channel 36 around needle 38 continuously while cleaning fluid is being introduced into the header through needle 38. Needle 38 of the Arnal device is not movable in response to fluid flow into a back flush position. Indeed, needle 38 does not have a distinct back flush position. Needle 38 can be moved into a stored position, as described a column 11, lines 23-38 of the reference specification, under the action of a bias means.

As disclosed at column 11, lines 24-27 of the reference specification, fluid pressure would force needle 38 or needle assembly 22 into an extended position for normal use. However, neither the specification nor figure 1A of the reference provides any indication of how this would be achieved. There is thus some question as to whether the reference contains a sufficient disclosure of this capability.

Thus, claim 1 of the present application clearly distinguishes over the disclosure of the applied reference at least by the following recitation:

said flow directing element being movable by fluid flow to said fluid inlet into a cleaning position in

which said fluid outlet end extends into the header when said first end of said housing is connected to the header and in which fluid can flow through said passage only in one direction toward said first end of said housing.

Claim 10 distinguishes patentably over the applied reference at least by the following recitation:

said flow directing element is movable parallel to the flow direction between the cleaning position and a back flush position in response to flow of fluid through said passage from said flow outlet end toward said fluid inlet end to provide a back flush flow path through said passage and around said flow directing element only when said flow directing element is in the back flush position.

As has already been pointed out, in the device disclosed by Arnal, the needle is not movable into a back flush position and is not moved into the stored position in response to flow of fluid. In addition, in the Arnal cleaning device, a back flush flow path is open at all times, regardless of whether the needle is in the operating position or in the stored position.

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The rejection presented in section 6 of the action is traversed on the grounds that the rejected claims should be considered allowable along with the claims from which they depend.

In view of the foregoing, it is requested that the rejections of record be reconsidered and withdrawn, that claims 1-14 be allowed and that the application be found in allowable condition.

If the above amendment should not now place the application in condition for allowance, the Examiner is invited to call undersigned counsel to resolve any remaining issues.

Respectfully submitted,

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